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EXAMINER	
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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,588	FRANCIS-LANG ET AL.	
	Examiner	Art Unit	
	SHERIDAN SWOPE	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2008 and 29 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,13,15,16,20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) *4,5,7-11,13,15,20 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6 and 16* is/are rejected.

7)☒ Claim(s) *1, 3, and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' responses of January 14 and September 29, 2008, to the action of July 12, 2007, is acknowledged. Claims 2, 12, 14, 17-19, and 21 have been cancelled and Claims 1, 3, 6, and 16 have been amended. Claims 1, 3-11, 13, 15, 16, 20, and 22-25 are pending. Claims 4, 5, 7-11, 13, 15, 20, and 22-25 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Claims 1, 3, 6, and 16 are hereby reexamined.

Claims-Objections

Claims 1, 3 and 16 are objected to for reciting non-elected subject matter. Applicants are reminded that the elected invention is directed to a method for identifying a candidate p21 pathway modulator by assessing the proliferation of a cultured cell expressing a casein kinase 1γ (CSNK1G).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Utility

Claims 1, 3, 6, and 16 rejected are under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Claims 1, 3, 6, and 16 recite a method for identifying a "candidate" p21 pathway modulator. To satisfy 35 U.S.C. 101, an invention must be "useful", i.e. be specific and substantial. A "specific utility" is *specific* to the subject matter claimed and can provide a well-defined and particular benefit to the public. To be substantial, the invention must be useful to the public as disclosed, not that it may prove useful at some future date after further research (see

MPEP 2107). In the instant case, the method is designed to merely identify a "candidate" p21 pathway modulator. Thus, the method fails to have a specific and substantial benefit to the public without further research to determine if the "candidate" modulator is, in fact, a modulator of a p21 pathway. Practicing the recited steps has no immediate benefit to the public.

Claims 1, 3, 6, and 16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 3, 6, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reason.

Rejection of Claims 1, 3, 6, and 16, because the phrase "agent-biased activity" renders the claims indefinite, is maintained. In response to this rejection, Applicants assert that the claims have been amended to remove said phrase; however, the claims have not been so amended.

Rejection of Claims 1, 3, 6, and 16 because the phrase "the system" lacks antecedent basis, is maintained. Said phrase should be corrected to "the assay system". In response to this rejection, Applicants assert that the claims have been amended to correct said phrase; however, the claims have not been so amended.

For Claims 1, 3, 6, and 16, the phrase "CSNK1G polypeptide" renders the claim indefinite. The specification states:

> "The term "CSNK1G polypeptide" refers to a full-length CSNK1G protein or a functionally active fragment or derivative thereof. A "functionally active" CSNK1G fragment or derivative exhibits one or more functional activities associated with a full-length, wild-type CSNK1G protein, such as antigenic or immunogenic activity, enzymatic activity, ability to bind natural cellular substrates, etc."

Said definition is only exemplary; the skilled artisan would not know the metes and bounds of the recited invention. In addition, the art teaches there are several isoforms of CSNK1G (Zhai et al, 1995; IDS); the specification fails to define which isoforms, and variants thereof, are encompassed.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

The rejection of Claims 1, 3, 6, and 16 under 35 U.S.C. 112, first paragraph/enablement, for the reasons explained in the prior action, is maintained.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(A) The recited method of identifying a candidate p21 pathway modulating agent using an assay system that detects a change in CSNK1G expression or activity is enabled.

(B) The specification provides sufficient guidance. For example, that CSNK1G polypeptides and the p21 pathway are involved in cell cycle regulation and cell growth, the

structure of CSNK1G polypeptides, agents that modulate the CSNK1G polypeptides and/or the p21 pathway, cell based assays, functional assays, and secondary, confirmation assays are taught.

These arguments are not found to be persuasive for the following reasons.

(A) Reply: The elected method is not directed to a method using an assay system that detects a change in CSNK1G expression or activity.

(B) Reply: It is acknowledged that these things are taught in general. It is also acknowledged that many cellular assays are known in the art. However, the specification fails to teach the full scope of the recited invention, which encompasses any method for identifying a candidate p21 pathway modulator by assessing the proliferation of any cultured cell expressing any CSNK1G for the following reasons.

(i) As explained above, the metes and bounds of the term "CSNK1G polypeptide" is indefinite. Thus, the specification fails to enable the skilled artisan to use any cell comprising any "CSNK1G polypeptide".

(ii) The elected invention is directed to a method for identifying a candidate p21 pathway modulator by assessing the proliferation of a cultured cell expressing a CSNK1G. Neither the specification nor the prior art provide sufficient guidance such that the skilled artisan can deduce that, if a test agent affects the proliferation of a cultured cell expressing a CSNK1G, said test agent is a p21 pathway modulator. Said deduction cannot be made because neither the specification nor the prior art provide evidence that a response of proliferation is diagnostic for modulation of the p21 pathway in any particular cell types. Clearly non-p21 pathways may be modulated by any test agent, thereby affecting proliferation and interpretation of the assay results. It would be undue experimentation for the skilled artisan to determine whether the p21

pathway is the sole pathway that mediates proliferation in all cell types. Without said experimentation, the skilled artisan would not know which cells can be successfully used in the recited method.

For these reasons and those explained in the prior action, rejection Claims 1, 3, 6, and 16 under 35 U.S.C. 112, first paragraph/enablement, is maintained.

Written Description

Rejection of Claims 1, 3, 6, and 16 under 35 U.S.C. 112, first paragraph/written description, for the reasons explained in the prior action, is maintained. In support of their request that said rejection be withdrawn, Applicants provide the following arguments.

(C) The specification describes a method of identifying a candidate p21 pathway modulating agent using cultured cells that express a CSNK1G polypeptide or nucleic acid and determining the expression or activity of CSNK1G in the assay system, wherein a change in CSNK1G expression or activity between the presence and absence of said candidate test agent indicates the presence of a candidate p21 pathway modulating agent.

(D) The specification thoroughly describes the characteristics of the CSNK1G polynucleotides and polypeptides as well as assays to be used.

These arguments are not found to be persuasive for the following reasons.

(C) Reply: The elected method is not directed to a method using an assay system that detects a change in CSNK1G expression or activity.

(D) Reply: The specification fails to sufficiently describe the recited invention, which encompasses any method for identifying a candidate p21 pathway modulator by assessing the proliferation of a cultured cell expressing a CSNK1G, for the following reasons. As explained

above, the metes and bounds of the term "CSNK1G polypeptide" is indefinite. Thus, the specification fails to sufficiently describe the use of any cell comprising any "CSNK1G polypeptide". The specification also fails to sufficiently describe those cells that can be used successfully in the elected invention. As explained above, useful cells have the characteristic that their proliferation is mediated solely by the p21 pathway; the specification teaches no such cells.

For these reasons and those explained in the prior action, rejection Claims 1, 3, 6, and 16 under 35 U.S.C. 112, first paragraph/written description, is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 6, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Funk et al, 2000 as evidenced by Kusuda et al, 2000 (IDS). Funk et al teach that bone marrow-derived dendritic cells from TNF-receptor knock-out mice survive in culture and proliferate in response to colony stimulating factor, while TNF inhibits colony stimulating factor-induced proliferation in wild-type cells (Fig 1c & 2a). Funk et al teach a second assay showing that the TNF-receptor deficient cells have reduced levels of p21 protein (Fig 2b), which they postulate contributes to the long-lasting proliferation of the cells. Thus, Funk et al teach a method of identifying a modulator of the p21 pathway, TNF, by measuring cell proliferation and a second assay measuring p21 protein levels. The dendritic cells of Funk et al are likely to express a

CSNK1G, as evidenced by Kusuda et al, 2000, which teaches that essentially all tissues express such kinases (Fig 2). Therefore, Claims 1, 2, 3, 6, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Funk et al, 2000 as evidenced by Kusuda et al, 2000.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donato et al, 1998 in view of Funk et al, 2000, as evidenced by Kusuda et al, 2000. Donato et al teach a process for identifying TNF and the protease inhibitor YVAD as modulators of the p21 pathway, wherein the process includes a cell survival assay (Fig 7) and measuring cleavage of p21 (Fig 9). Donato et al do not teach a process for identifying modulators of the p21 pathway, wherein the process includes a cell proliferation assay. As described above, Funk et al teach a cell proliferation assay. It would have been obvious to a person of ordinary skill in the art to combine the teachings of Donato et al and Funk et al to develop a process for identifying TNF and the protease inhibitor YVAD as modulators of the p21 pathway, wherein the process includes a cell proliferation assay. Motivation to do so is provided by the desire to confirm that TNF and YVAD affect cell proliferation via the p21 pathway. The expectation of success is high, as cell proliferation assays are well-known in the art. The ME-180 cells of Donato et al are likely to express a CSNK1G, as evidenced by Kusuda et al, which teaches that essentially all tissues express such kinases (Fig 2). Therefore, Claims 1, 2,7 6, and 16 are rejected under 35

U.S.C. 103(a) as being unpatentable over Donato et al, 1998 in view of Funk et al, 2000, as evidenced by Kusuda et al, 2000.

Applicants' Arguments

In support of their request that the prior rejections under 35 U.S.C. 102(b) and 103(a) be withdrawn, Applicants provide the following arguments, which are relevant to the rejections above.

(E) The Office has overlooked the inventive aspect of the claimed method of identifying a candidate p21 pathway modulating agent using an assay system that detects a change in CSNK1G expression or activity.

(F) The reference(s) cited fails to contemplate any [functional] association between casein kinase I and p21.

(E) Reply: As per Applicants' response of April 27, 2007, the elected invention is directed to a method for identifying a modulator using a cellular proliferation assay system comprising a casein kinase 1γ. The elected invention is not directed to a method using an assay system that detects a change in CSNK1G expression or activity.

(E) Reply: The claims fail to recite any limitation of a functional association between CSNK1G and p21. The claims merely recite using a cell comprising a CSNK1G.

Allowable Subject Matter

No claims are allowable.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants'

remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
Primary Examiner, Art Unit 1652